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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,455	04/09/2004	Roger Akers	SYNT-P006US	1352

7590 05/17/2005

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,455

Applicant(s)

AKERS ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 20-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/2/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 20-55 in the reply filed on 2/11/05 is acknowledged.
2. Claims 20-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/11/05.

Information Disclosure Statement

3. The information disclosure statement filed 12/2/04 has been considered and made of record.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 2-4, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are indefinite because it is not clear how the recited connector filter or outlet filters that transverse the first and second culture compartment as recited in the claims structurally cooperate with the previously recited inlet, bore and/or outlets of the device.

Claims 14 and 15 are indefinite for the same reasons as set forth with respect to claims 2-4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marx et al.(US 6,255,106) in view of Ghezzi et al.(US 5,194,157).

The reference of Marx et al. discloses a culture system that includes the use of two serially connected membrane bioreactors (See column 1, lines 23-25, 37-39, 57-62; column 2, lines 25, 48-52; and Figure 1). The serially connected bioreactors would include a first bioreactor includes a tubular housing with first and second end pieces wherein the end pieces are provided in communication with the tubular membranes separating the inlet and outlets from the cell culture space. The same would hold true for the second bioreactor. The membrane of the first bioreactor would meet the claimed connection filter and the membrane of the second bioreactor would meet the claimed outlet filter.

While the reference discloses the serial connection of the bioreactors, the reference does not recite that the bioreactors are connected using a fluid connector with a through bore.

The reference of Ghezzi et al. discloses that it is known in the art to employ a fluid connector (6) that includes a through bore when serially connecting two membrane devices.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the fluid connected disclosed by Ghezzi et al. when serially connecting the bioreactors of the primary reference for the known and expected result of providing an art recognized means for serially connecting membrane devices.

With respect to the membrane properties and/or bioreactor volumes, the reference of Marx et al. discloses optimization of the bioreactors based merely on the specifics of the cells to be cultured (See column 1, lines 37-40).

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With respect to the use of fluid fill ports and gas vents, if not inherently associated with the bioreactors, their use would have been obvious for the known and expected result of providing an art recognized means for adding cells and/or sampling the cell culture space.

With respect to the use of identifiers, such as bar codes, it would have been obvious to one of ordinary skill in the art to provide the bioreactor chambers with identifiers, especially bar codes, for the known and expected result of providing a means notoriously well known in the art for positive identification of a component part.

10. Claims 5 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marx et al.(US 6,255,106) in view of Ghezzi et al.(US 5,194,157) taken further in view of Schwarz et al.(US 5,026,650) or Akers et al.(US 2004/0110273).

The combination of the references of Marx et al. and Ghezzi et al. has been discussed above.

The above claims differ by reciting that the membrane includes a membrane support.

The reference of Schwarz et al. discloses that it is known in the art to provide a membrane bioreactor using a single tubular membrane (40) provided on a membrane support (32).

The reference of Akers et al. discloses that it is known in the art to provide a membrane bioreactor using a single tubular membrane (27) provided on a membrane support (28) (See Figures 1-3).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to employ a membrane bioreactor with a membrane configuration as suggested by the

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reference of Schwarz et al. or Akers et al. for the known and expected result of providing an art recognized means for separating a cell culture space from a nutrient fluid flow. Use of a support ensures structural integrity with respect to the membrane when traversing a long chamber.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB